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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,647	04/14/2004	Alagu P. Thiruvengadam	A8709	4915

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EXAMINER	
KIM, TAEYOON	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/823,647	THIRUVENGADAM ET AL.	
	Examiner	Art Unit	
	Taeyoon Kim	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-47 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-47 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-26 and 44, drawn to a method for diagnosing a biopolar disease comparing a ratio of membrane potential of non-biopolar control, bipolar control and a known biopolar patient, wherein the ratio is obtained from the cells incubated in the absence of K^+ and presence of a compound altering Na^+K^+ ATPase activity to membrane potential of cells incubated in the presence of K^+ and presence of a compound altering Na^+K^+ ATPase activity, classified in class 435, subclass 4.

II. Claims 27-32 and 45, drawn to a method for diagnosing a biopolar disease comparing a ratio of membrane potential of non-biopolar control, bipolar control and a known biopolar patient, wherein the ratio is obtained from the cells incubated in the absence of compound altering Na^+K^+ ATPase activity to membrane potential of cells incubated in the presence a compound altering Na^+K^+ ATPase activity, classified in class 435, subclass 4.

III. Claims 33, 34 and 46, drawn to a method for diagnosing a biopolar disease comparing a relative ratio of membrane potential of non-biopolar control, bipolar control and a known biopolar patient, wherein the relative ratio is obtained from a ratio I obtained from membrane potential of cells incubated in the absence of K^+ and presence of a compound altering Na^+K^+ ATPase

activity to membrane potential of cells incubated in the absence of K^+ and absence of a compound altering Na^+K^+ ATPase activity, and a ratio II obtained from membrane potential of cells incubated in the presence of K^+ and presence of a compound altering Na^+K^+ ATPase activity to membrane potential of cells incubated in the presence of K^+ and absence of a compound altering Na^+K^+ ATPase activity, classified in class 435, subclass 4.

IV. Claims 35-38 and 47, drawn to a method for diagnosing a biopolar disease comparing a mean rate of repolarization obtained from cells incubated in the absence of K^+ and presence of a compound altering Na^+K^+ ATPase activity to membrane potential of cells incubated in the absence of K^+ and absence of a compound altering Na^+K^+ ATPase activity, classified in class 435, subclass 4.

V. Claims 39-43, drawn to a method for diagnosing an unipolar disease, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

The inventions Groups I and II-V are distinct. Inventions are distinct if the inventions as claimed are not connected in at least one of design, operation, or effect (e.g., can be made by, or used in a materially different process) and wherein at least one invention is PATENTABLE (novel and nonobvious) OVER THE OTHER (though they may each be unpatentable over the prior art) (MPEP § 802.01).

The processes are distinct from one another because they recite different and distinct steps which lead to different and distinct products.

The method of Group I invention is different from the method of Group II invention because membrane potentials of the former method are obtained from different combinations of K^+ and Na^+K^+ ATPase activity from the latter method. Group I invention is based on the absence or presence of K^+ while the Group II invention is based on the absence or presence of Na^+K^+ ATPase activity.

The method of Group I or II invention requires to obtain the ratio of membrane potential of cells in the absence and presence of K^+, and in the presence of Na^+K^+ ATPase activity, whereas the method of Group III requires to obtain the relative ratio of membrane potential from the condition of the presence or absence of a compound altering Na^+K^+ ATPase activity.

The method of Group I, II or III invention is distinct from the method of Group IV invention because Group IV invention requires two ratios (I and II) whereas Group I, II or III does not require two ratios for diagnosing bipolar disease.

The method of Group I, II or III invention is distinct from the method of Group V invention because the methods utilize cells from different sources; that is the Group I, II, or III use cells from biopolar disease patients whereas the Group V use cells from unipolar disease patient.

An undue burden would ensue from the examination of multiple methods which have distinct steps and end points. Burden lies not only in the search of US Patents, but in the

search for literature and foreign patents and examination of the claim language and specification for compliance with the statutes concerning new matter and distinctness.

The several inventions above are independent and distinct each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group.

Because these inventions are distinct for the reasons given above and the search required for one group is not required for the other groups, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species:

A. Type of compound altering Na^+K^+ ATPase: valinomycin, monensin, monensin decyl ester, gramicidin, p-chloromercurybenzenesulfonate (PCMBS), veratridine, ethacrynate, dopamine, a catecholamine, a phorbol ester, ouabain, lithium, valproate, lamotrigine, cocaine, nicotine, R0-31-8220, oxymetazoline, calcineurin, topiramate, a peptide hormone, sorbitol, a diuretic (Claims 8, 31, 34, 38 and 41)

B. Type of cells for the method: lymphoblasts, erythrocytes, platelets, leukocytes, macrophages, monocytes, dendritic cells, fibroblasts, epidermal cells, mucosal

tissue cells, cells in the cerebrospinal fluid, hair cells, cells in whole blood (Claim 24)

The species are independent or distinct because they do not belong to any art recognized group nor do they share a substantial structural feature.

In addition, if Group I is elected, a further election of species must be made from Groups A and B. If Group II, III, IV or V is elected, a further election of species must be made from Group A.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and ***a listing of all claims readable thereon***, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Taeyoon Kim
Patent Examiner
Art Unit 1651